

**VA Rules for Allowable Signatures for HIPAA Authorizations for  
Participants with Impaired Decision-Making Capacity**

- Protocols that enroll decisionally impaired subjects may need two different individuals as signatories for the research Informed Consent and the HIPAA Authorization. VA rules for Legally Authorized Representative (LAR) to sign informed consent ARE DIFFERENT FROM the VA rules for a Personal Representative who is allowed to sign HIPAA authorizations for decisionally impaired participants.
- **Definitions:**
  - **Legally Authorized Representative.** Legally Authorized Representative (LAR) means an individual or judicial or other body authorized under applicable law to **consent** on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research (45 CFR 46.102(c)). LARs allow for a hierarchy of family members and significant others to sign research informed consent documents.
  - **Personal Representative.** A Personal Representative is a person, who under applicable law, has authority to act on behalf of the individual. This may include Durable Power of Attorney (DPA) for Health Care, legal guardianship of an individual, the executor of the estate of a deceased individual, or someone under Federal, state, local or tribal law with such authority (e.g., parent of a minor). *A personal representative for the purposes of VHA Handbook 1605.1 does not necessarily equate to a surrogate for the informed consent process (see 38 CFR Section 17.32(e) for authorized surrogates for informed consent).*
- The VA thus makes a distinction between what types of individuals are permissible to sign HIPAA authorizations and informed consent forms on behalf of decisionally impaired research participants: LARs are authorized to sign informed consents. Personal representatives are authorized to sign HIPAA Authorizations for release of personal health information. Some but not all LARs may also be qualified to sign HIPAA authorizations:
  - Protocols with decisionally impaired subjects must ensure that a Personal Representative with a Durable Power of Attorney for Health Care or court-appointed legal guardianship has signed the HIPAA Authorization.
  - If the LAR and Personal Representative are one in the same (i.e. the LAR is a DPA or a legal guardian), then that individual may sign both the Informed Consent and HIPAA Authorization.
- **Bottom Line:**
  - If you believe your study could involve participation of decisionally impaired individuals **and**

- if use or disclosure of PHI is required for your project, **and**
  - if you will not be able to guarantee that you will always have a DPA or legal guardian who is the LAR,
- then you should request a waiver or alteration of HIPAA authorization from the IRB for your study.

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